



**UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
---------------	-------------	----------------------	---------------------

08/722,045 10/04/96 FREEMAN

V 96-1252.US

EXAMINER

15M1/1016

MARY L. SEVERSON  
ELAN PHARMACEUTICAL RESEARCH CORPORATION  
1300 GOULD DRIVE  
GAINESVILLE GA 30504

ARHWE, P PAPER NUMBER

1502

DATE MAILED: 10/16/97

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 10-04-96 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

**Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:**

- |   |  |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input checked="" type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449.      | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152.                  |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474.     | 6. <input type="checkbox"/>  |

**Part II SUMMARY OF ACTION**

1. ☒ Claims 1-20 are pending in the application.  
Of the above, claims \_\_\_\_\_ are withdrawn from consideration.
2. ☐ Claims \_\_\_\_\_ have been cancelled.
3. ☐ Claims \_\_\_\_\_ are allowed.
4. ☒ Claims 1-20 are rejected.
5. ☐ Claims \_\_\_\_\_ are objected to.
6. ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.
7. ☐ This application has been filed with Informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed \_\_\_\_\_, has been ☐ approved; ☐ disapproved (see explanation).
12. ☒ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☒ been received ☐ not been received  
☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

SN 08/722,045  
PSW

EXAMINER'S ACTION

Art Unit: 1502

Claims 1-20 are pending in this application and considered below.

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wheling et al. (US pat.# 5,178,878) and Wong et al. (US pat.# 4,824,675).

Wheling et al. show oral microcapsular dosage forms comprising an analgesic (column 4, line 58), pharmaceutical agent, a effervescent disintegration agent and a polymeric protective material (column 11; column 9, lines 39-68).

The claims differ in reciting a particular combination of actives, plus use of a particular polymer.

Wong et al. teach particles or granules comprising polylactide (column 13, lines 38-49 and column 16, line 5), an affervescent couple (column 12, lines 38-68), and an active agent selected from analgesics, antagonists, calcium and channel inhibitors (column 16, lines 47-49 and 54). Note that the use of diltiazem, captopril or nitrendipine is shown (column 17, lines 36 and 39).

Since Wehling et al. disclose the conventionality of dosage forms such as that claimed, it would have been obvious to employ the microparticles of '878 by selecting polylactide polymer in conjunction with nifedipine, diltiazem, capropril analgesics or mixtures thereof to obtain the known and expected combination of benefits.


Art Unit: 1502

Oshlack et al. (US pat #5,500,227 of cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pamela S. Webber whose telephone number is (703) 308-4427. The examiner can normally be reached on Monday-Thursday from 8:30 a.m. to 6:00 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for this Group is (703) 305-5408.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-2361.

  
**Pamela S. Webber:eap**  
Patent Examiner

October 7, 1997

  
THURMAN K. PAGE  
SUPERVISOR